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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/550,787  | 09/27/2005  | Gary W Procop        | CCF-6566PCT/US      | 9417             |
| 26294 7590 11/09/2009<br>TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P.<br>1300 EAST NINTH STREET, SUITE 1700<br>CLEVEVLAND, OH 44114 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| SITTON, JEHANNE SOUAYA  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1634  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/550,787

**Applicant(s)**

PROCOP, GARY W

**Examiner**

Jehanne S. Sitton

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 9-2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II, SEQ ID NO: 3 in the reply filed on 10/26/2007 is acknowledged. Claims 23-29 read on the elected invention and are examined herein. Claims 1-22 and 30 are withdrawn from consideration as being drawn to a non elected invention.

### ***Priority***

2. The instantly pending claims are directed to "the prg gene" of Salmonella but do not specify which gene. As such, the claims are not awarded benefit of priority to provisional application 60/466,398, because this broad disclosure is not supported by the '398 application. Accordingly, the effective filing date of the instantly pending claims is 4/27/2004.

### ***Claim Objections***

3. Claim 26 is objected to because of the following informalities: The claim appears to contain a typographical error. The recitation of "on" in line 2 appears to be incorrect, and should read "one". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 lacks antecedent basis with regard to "the oligonucleotide hybridization probe" because claim 27 is directed to two hybridization probes. It is not clear which hybridization probe is referred to in claim 28.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (Klein et al; Infection and Immunity, June 2000, vol 68, pages 3368-3376) and Wittwer (US Patent 6,245,514) in view of Benson (US Patent 6,878,517) and Genbank Accession number U21676.1 (1996) as evidenced by Bellin (Bellin et al; Journal of Clinical Microbiology, January 2001, vol. 39, pages 370-374) or Ellingson (US Pregrant Publication 2003/0022214).

Klein teaches that Salmonella infections are an important health problem and that pathogenic Salmonella species cause infections that range in severity from gastroenteritis to life threatening systemic dissemination (page 3368, col 1). Klein teaches that genes in Salmonella include the prgH, prgI, prgJ, prgK, orgA, orgB and orgC genes.

With regard to claims 23-29, Wittwer teaches an improved method for analyzing target nucleic acids present in a sample using PCR for identification of PCR products by their fluorescence melting curves (see col 3) in a rapid temperature cycler. Wittwer teaches methods which utilize two PCR primers and two hybridization probes, wherein the probes are labeled

with a fluorescent donor and fluorescent acceptor, respectively, and detection of PCR products is achieved by resonance energy transfer between the labeled probes which hybridize internal to the PCR primers (see col 5).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to detect Salmonella in a sample by using the Lightcycler PCR based method of Wittwer for the effective detection of Salmonella in the sample.

Klein and Wittwer do not specifically teach which gene in Salmonella to target, however Benson illustrates nucleic acid based hybridization methods for detecting Salmonella in a sample and specifically teaches that the *prgK* gene from Salmonella can be used as a diagnostic target nucleic acid for that organism (see cols 13, line 60-col 14, line 12). Additionally, the nucleic acid sequence of the *prgK* gene was known in the art at the time the invention was made and is taught by Genbank Accession number U21676.1. Notably, SEQ ID NO: 3 (claim 28) is taught at nucleotides 3272-3465 (complement), SEQ ID NO: 8 (claim 29) is taught at nucleotides 3378-3409, and SEQ ID NO: 9 is taught at nucleotides 3412-3425 (claim 29). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to construct probes and primers to the *prgK* gene, as taught by Wittwer, including the instantly claimed SEQ ID NOS, for the detection of Salmonella as taught by Benson, with a reasonable expectation of success.

A large number of references were published at the time the invention was made in the use of Lightcycler PCR to detect specific nucleic acid targets in methods of identifying microbial species.

For example, Bellin teaches a method for the multiplex real time PCR detection of Enterohemorrhagic (EHEC) E. coli using a primer pair and two fluorescent hybridization probes to detect the shiga toxin 1 (stx1) and shiga toxin 2 genes (stx2) (see Table 3). Bellin teaches a method wherein different strains of E. coli were detected in human stool and that FRET hybridization probes were marked with LightCycler Red 705 and Light Cycler Red 640 as acceptor dyes (see page 370, col. 2 “PCR primers and Probes; instant claim 8) and fluorescein as the donor (table 3, instant claim 7).

Ellingson teaches detection of Salmonella using real time PCR amplification and detection of the amplification product by fluorescence resonance energy transfer using a pair of labeled polynucleotides.

Absent secondary considerations, the claimed invention is considered unpatentable over the teachings of the cited prior art. Klein provides motivation to detect Salmonella in a sample. Wittwer teaches the successful detection of target nucleic acids in a sample and Benson teaches to target the prgK gene for detection of Salmonella. Further, the successful use of lightcycler PCR for detection of microbial species in a sample is illustrated by the teachings of Bellin and Ellingson.

7. NO claims are allowable over the cited prior art.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Mondays from 9:00 AM to 1:00 PM, and Tuesdays & Thursdays from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571) 272-0731. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Jehanne Sitton/  
Primary Examiner  
Art Unit 1634